



## In the United States Patent & Trademark Office

In re New Patent Application of:

**Offord, R. *et al.***

Examiner:

Serial No.: To Be Assigned

Art Unit:

Filed: Herewith

Atty. Dkt.: 3504.246 GRFN 026/04-US

For: **N-Terminal Modification of  
RANTES and Methods of Use**

### **Information Disclosure Statement Pursuant to 37 C.F.R. § 1.97(b)(1)**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of those documents that are not enclosed herewith have been previously provided to the U.S. Patent & Trademark Office with respect to U.S. Patent Application Serial No. 08/537,928, from which the present application claims priority.

The Examiner is requested to contact the undersigned in the event that any of the cited documents cannot be located, so that replacement copies can be expeditiously provided to the Examiner.

This Information Disclosure Statement is being submitted prior to an Initial Office Action. No fee is accordingly believed due for consideration of this Information Disclosure Statement. However, if the Commissioner determines that an additional fee is required in for consideration of this Information Disclosure Statement, the U.S. Patent

and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to Deposit Account No. 50-0548 referencing docket number 3504.244.

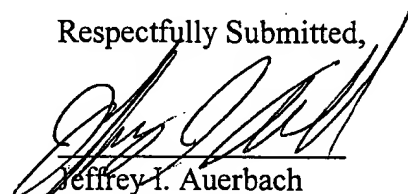
The submission of the listed and appended documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicants do not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Applicants respectfully request that the documents listed on the accompanying Form PTO-1449 be considered and made of record in the present application. Applicants further request that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

While the listed references are considered relevant to the prosecution of the present application, it is submitted that the references, either alone or in combination, do not detract from the patentability of the claimed invention.

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Respectfully Submitted,

  
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Form PTO-1449  
(REV. 8-83)

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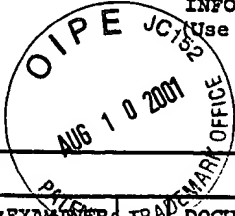
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INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)



APPLICANT:  
Offord, et al.

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GROUP

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	P1 5,739,208	4/14/1998	Harris	525	54.1	6/7/1995
	P2 5,672,662	9/30/1997	Harris, et al.	525	408	9/30/1997
	P3 5,122,614	6/16/92	Zalipsky	548/520		6/16/1992
	P4					
	P5					
	P6					
	P7					
	P8					
	P9					
	P10					
	P11					

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FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	F1 96/34878	11/7/1996	WO	6			
	F2 96/17935	6/13/1996	WO	6			
	F3 0 605 963 A2	12/7/1993	EP	5			
	F4						

OTHER PUBLICATIONS (including Author, Title, Date, Pertinent Pages, Etc.)

D1	Abuchowski, Abraham, et al., "Alteration of Immunological Properties of Bovine Serum Albumin by Covalent Attachment of Polyethylene Glycol", <u>J.Biol.Chem.</u> , Vol. 252, No. 11, pp. 3578-3581 (1977)
D2	Alkhatib, Ghalib, et al., "CC CKR5: A RANTES, MIP-1 $\alpha$ , MIP-1 $\beta$ Receptor as a Fusion Cofactor for Macrophage-Tropic HIV-1", <u>Science</u> , Vol.272, pp.1955-58 (1996)

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Form PTO-1449 (REV. 8-83)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. <b>3504.246</b>		SERIAL NO. <b>To Be Assigned</b>	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANT: <b>Offord, et al.</b>			
				FILING DATE <b>Herewith</b>		GROUP	
OTHER PUBLICATIONS (including Author, Title, Date, Pertinent Pages, Etc.)							
	D3	Angiolillo, et al., "A Role for the Interferon-Inducible Protein 10 in Inhibition of Angiogenesis by Interleukin-12", <u>Annals NY Acad. Sci.</u> , Vol.795, pp.158-167 (1996)					
	D4	Arenzana-Seisdedos, Fernando, et al., "HIV Blocked by Chemokine Antagonist", <u>Nature</u> , Vol.383, p.400 (1996)					
	D5	Berger, et al., "A New Classification for HIV-1", <u>Nature</u> , Vol.391, p.240 (1998)					
	D6	Cairns, et al., "Chemokines and HIV-1 Second Receptors: The Therapeutic Connection", <u>Nature Med.</u> , Vol.4, No.5, pp.563-568 (1998)					
	D7	Chen, et al., "Genetically Divergent Strains of Simian Immunodeficiency Virus Use CCR5 as a Co-Receptor for Entry", <u>J.Virol.</u> , Vol.71, No.4, pp.2705-2714 (1997)					
	D8	Chesebro, et al., "Mapping of Independent V3 Envelope Determinants of Human Immunodeficiency Virus Type 1 Macrophage Tropism and Syncytium Formation in Lymphocytes", <u>J.Virol.</u> , Vol.70, No. 12, pp.9055-9059 (1996)					
	D9	Choe, et al., "The $\beta$ -Chemokine Receptors CCR3 and CCR5 Facilitate Infection by Primary HIV-1 Isolates", <u>Cell</u> , Vol.85, pp.1135-1148 (1996)					
	D10	Cocchi, et al., "Identification of RANTES, MIP-1 $\alpha$ , and MIP- $\beta$ as the Major HIV-Suppressive Factors Produced by CD8+ T Cells", <u>Science</u> , Vol. 270, pp.1811-1815 (1995)					
	D11	Cocchi, et al., "The V3 Domain of the HIV-1 gp 120 Envelope Glycoprotein is Critical for Chemokine-Mediated Blockade of Infection", <u>Nature Med.</u> , Vol. 2, No.11, pp. 1244-1247 (1996)					
	D12	Connor, et al., "Increased Viral Burden and Cytopathicity Correlate Temporally with CD4+ T-Lymphocyte Decline and Clinical Progression in Human Immunodeficiency Virus Type 1-Infected Individuals", <u>J.Virol.</u> , Vol.67, No.4, pp.1772-1777 (1993)					
	D13	Danesi, et al., "Inhibition of Experimental Angiogenesis by the Somatostatin Analogue Octreotide Acetate (SMS 201-995)", <u>Clin.Cancer Res.</u> , Vol.3, pp.265-272 (1997)					
	D14	Datema, et al., "Antiviral Efficacy in Vivo of the Anti-Human Immunodeficiency Virus Bicyclam SDZ SID 791 (JM3100), an Inhibitor of Infectious Cell Entry", <u>Antimicrob. Agents and Chemo.</u> , Vol. 40, No3., pp.750-754 (1996)					
	D15	Dawson, et al., "Synthesis of Proteins by Native Chemical Ligation", <u>Science</u> , Vol. 266, pp. 776-779 (1994)					
	D16	Deng, et al., "Identification of a Major Co-Receptor for Primary Isolates of HIV-1", <u>Nature</u> , Vol. 381, pp.661-666 (1996)					
	D17	Doranz, et al., "A Dual-Tropic Primary HIV-1 Isolate That Uses Fusin and the $\beta$ -Chemokine Receptors CKR-5, CKR-3, and CKR-2B as Fusion Cofactors", <u>Cell</u> , Vol. 85, pp.1149-1158 (1996)					
	D18	Friedlander, et al. "Definition of Two Angiogenic Pathways by Distinct $\alpha$ , Integrins", <u>Science</u> , Vol.270, pp.1500-1502 (1995)					
	D19	Gao, et al., "Structure and Functional Expression of the Human Macrophage Inflammatory Protein 1 $\alpha$ /RANTES Receptor", <u>J.Exp.Med.</u> , Vol. 177, pp. 1421-1427 (1993)					
	D20	Gauduin, et al., "Passive Immunization With a Human Monoclonal Antibody Protects hu-PBL-SCID Mice Against Challenge by Primary Isolates of HIV-1", <u>Nat.Med.</u> , Vol. 3, No.12, pp.1389-1393 (1997)					
	D21	Hojo, Hironobu and Aimoto, Saburo, "Polypeptide Synthesis Using the S-Alkyl Thioester of a Partially Protected Peptide Segment. Synthesis of the DNA-Binding Domain of c-Myb Protein (142-193)-NH <sub>2</sub> ", <u>Bull.Chem.Soc.Jpn.</u> , Vol. 64, pp. 111-117 (1991)					
EXAMINER				DATE CONSIDERED			

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Form PTO-1449 (REV. 8-83)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.  <div style="text-align: center; font-size: 1.2em;">3504.246</div>	SERIAL NO.  <div style="text-align: center; font-size: 1.2em;">To Be Assigned</div>
<div style="border: 1px solid black; border-radius: 50%; padding: 10px; display: inline-block; text-align: center;">             OIPE JC152 AUG 10 2001 PATENT &amp; TRADEMARK OFFICE           </div> <div style="margin-top: 10px;">             INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)           </div>		APPLICANT: Offord, et al.	
OTHER PUBLICATIONS (including Author, Title, Date, Pertinent Pages, Etc.)		FILING DATE <div style="text-align: center;">Herewith</div>	GROUP
D22		Jose, et al., "Eotaxin: A Potent Eosinophil Chemoattractant Cytokine Detected in a Guinea Pig Model of Allergic Airways Inflammation", <u>J.Exp.Med.</u> , Vol.179, pp. 881-887 (1994)	
D23		Mack, et al., "Aminooxypentane-RANTES Induces CCR5 Internalization but Inhibits Recycling: A Novel Inhibitory Mechanism of HIV Infectivity", <u>J.Exp.Med.</u> , Vol. 187, No.8, pp. 1215-1224 (1998)	
D24		Mosier, et al., "Transfer of a Functional Human Immune System to Mice With Severe Combined Immunodeficiency", <u>Nature</u> , Vol. 335, pp. 256-259 (1988)	
D25		Mosier, et al., "Human Immunodeficiency Virus Infection of Human-PBL-SCID Mice", <u>Science</u> , Vol. 251, pp.791-794 (1991)	
D26		Mosier, et al., "Rapid Loss of CD4+ T Cells in Human-PBL-SCID Mice by Noncytopathic HIV Isolates", <u>Science</u> , Vol. 260, pp. 689-692 (1993)	
D27		Mosier, Donald, "Human Immunodeficiency Virus Infection of Human Cells Transplanted to Severe Combined Immunodeficient Mice", <u>Adv.in Immun.</u> , Vol. 63, pp. 79-125 (1996)	
D28		McKnight, et al., "HIV-2 and SIV Infection of Nonprimate Cell Lines Expressing Human CD4: Restrictions to Replication at Distinct Stages", <u>Virology</u> , Vol. 201, pp.8-18 (1994)	
D29		Neote, et al., "Molecular Cloning, Functional Expression, and Signaling Characteristics of a C-C Chemokine Receptor", <u>Cell</u> , Vol. 72, pp.415-425 (1993)	
D30		Oikawa, et al., "Angiogenic Factor of a rat Mammary Tumor Cell Line (RMT-1) (I). Secretion of two Distinct Angiogenic Factors Into Serum-Free Conditioned Medium by RMT-1 Cells", <u>Cancer Lett.</u> , Vol. 59, pp. 57-66 (1991)	
D31		Parren, et al., "Protection Against HIV-1 Infection in hu-PBL-SCID Mice by Passive Immunization With a Neutralizing Human Monoclonal Antibody Against the gp120 CD4-Binding Site", <u>AIDS</u> , Vol.9, No.6, pp. 1-6 (1995)	
D32		Paxton, et al., "Reduced HIV-1 Infectability of CD4+ Lymphocytes From Exposed-Uninfected Individuals: Association With Low Expression of CCR5 AND High Production of $\beta$ -Chemokines", <u>Virology</u> , Vol. 244, pp.66-73 (1998)	
D33		Picchio, et al., "Chemokine Receptor CCR5 Genotype Influences the Kinetics of Human Immunodeficiency Virus Type 1 Infection in Human PBL-SCID Mice", <u>J.Virol.</u> , Vol. 71, No. 9, pp 7124-7127 (1997)	
D34		Picchio, et al., "The Cell Tropism of Human Immunodeficiency Virus Type 1 Determines the Kinetics of Plasma Viremia in SCID Mice Reconstituted With Human Peripheral Blood Leukocytes", <u>J.Virol.</u> , Vol. 72, No.3, pp.2002-2009 (1998)	
D35		Proudfoot, et al., "Extension of Recombinant Human RANTES by the Retention of the Initiating Methionine Produces a Potent Antagonist", <u>J.Biol.Chem.</u> , Vol. 271, No. 5, pp.2599-2603 (1996)	
D36		Risau, Werner, "Mechanisms of Angiogenesis", <u>Nature</u> , Vol. 386, pp.671-674 (1997)	
D37		Schnolzer, et al., "In situ neutralization in Boc-chemistry Solid Phase Peptide Synthesis", <u>J.Peptide Protein Res.</u> , Vol. 40, pp. 180-193 (1992)	
D38		Schuitemaker, et al., "Monocytotropic Human Immunodeficiency Virus Type 1 (HIV-1) Variants Detectable in all Stages of HIV-1 Infection Lack T-Cell Line Tropism and Syncytium-Inducing Ability in Primary T-Cell Culture", <u>J.Virol.</u> , Vol. 65, No.1, pp. 356-363 (1991)	
D39		Simmons, et al., "Potent Inhibition of HIV-1 Infectivity in Macrophages and Lymphocytes by a Novel CCR5 Antagonist", <u>Science</u> , Vol.276, PP.276-279 (1997)	
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OTHER PUBLICATIONS (including Author, Title, Date, Pertinent Pages, Etc.)

D40	Simmons, et al., "Primary, Syncytium-Inducing Human Immunodeficiency Virus Type 1 Isolates Are Dual-Tropic and Most Can Use Either Lestr or CCR5 as Coreceptors for Virus Entry", <u>J.Virol.</u> , Vol. 70, No. 12, pp.8355-8360 (1996)
D41	Speck, et al., "Selective Employment of Chemokine Receptors as Human Immunodeficiency Virus Type 1 Coreceptors Determined by Individual Amino Acids within the Envelope V3 Loop", <u>J.Virol.</u> , Vol. 71, No. 9, pp.7136-7139 (1997)
D42	Tersmette, et al., "Association Between Biological Properties of Human Immunodeficiency Virus Variants and Risk for Aids and Aids Mortality", <u>Lancet</u> , pp. 983-985 (1989)
D43	Trkola, et al., "CD4-Dependent, Antibody-Sensitive Interactions Between HIV-1 and its Coreceptor CCR-5", <u>Nature</u> , Vol. 384, pp. 184-187 (1996)
D44	Trkola, et al., "Genetic Subtype-Independent Inhibition of Human Immunodeficiency Virus Type 1 Replication by CC and CXC Chemokines", <u>J.Virol.</u> , Vol. 72, No. 1, pp. 396-404 (1998)
D45	Tsutsumi, et al., "Chemical Modification of Natural Human Tumor Necrosis Factor- $\alpha$ With Polyethylene Glycol Increases its Anti-Tumor Potency", <u>Jpn.J. Cancer Res.</u> , Vol. 85, pp. 9-12 (1994)
D46	Weiss, et al., "Plasma Levels of Monocyte Chemoattractant Protein-1 but not Those of Macrophage Inhibitory Protein-1 $\alpha$ and RANTES Correlate with Virus Load in Human Immunodeficiency Virus Infection", <u>J.Infect.Dis.</u> , Vol. 176, No. 6, pp. 1621-1624 (1997)
D47	Wu, et al., "CCRS Levels and Expression Pattern Correlate with Infectability by Macrophage-Tropic HIV-1 In Vitro", <u>J.Exp.Med.</u> , Vol. 185, No. 9, pp. 1681-1691 (1997)
D48	Zalipsky, Samuel, "Functionalized Poly(ethylene glycol) for Preparation of Biologically Relevant Conjugates", <u>Bioconj. Chem.</u> , Vol. 6, pp. 150-165 (1995)

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	P1					

FOREIGN PATENT DOCUMENTS							
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	F1						

OTHER PUBLICATIONS (including Author, Title, Date, Pertinent Pages, Etc.)	
D1	Noso, Norio, et al., "Identification of a N-Terminally Truncated Form of the Chemokine RANTES and Granulocyte-Macrophage Colony-Stimulating Factor as Major Eosinophil Attractants Released by Cytokine-Stimulated Dermal Fibroblasts", <u>Journal of Immunology</u> , Vol. 156, no.5, pgs. 1946-1953 (1996)
D2	International Search Report for PCT/US98/18204
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